Israel Biomedical Innovations Ltd.
2 Ha-Eshel St. P.O.BOX 3081
Caesarea Industrial Park 38900, Israel

JUL 2 9 2013

510(K) SUMMARY

[as required by section 807.92(c)]

EndoFast Reliant™ SCP and EndoFast Reliant™ LAP

510(k) Number K_____

Applicant's Name:

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Contact Person:

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Prepared On:

January 7, 2013

Trade Name:

EndoFast Reliant™ SCP
EndoFast Reliant™ LAP

****SCP = Sacrocolpopexy***
****LAP = Laparoscopic***

Classification:

Name: Fixation, non-absorbable or absorbable, for pelvic use
Product Code: PBQ
Regulation No: 884.4530
Class: 2
Classification Panel: Obstetrics/Gynecology

Name: Mesh, Surgical, Polymeric

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Name: Mesh, surgical, synthetic, urogynecologic, for apical vaginal and uterine prolapse, transabdominally placed.
Product Code: OTO
Regulation No: 878.3300
Class: 2
Classification Panel: Obstetrics/Gynecology

Predicate Devices:
EndoFast Reliant™ System–K080836
Autosuture™ TACKER - K090470

Device Description:
The EndoFast Reliant™ SCP (Sacrocolpopexy) is a sterile, single use system which consists of the following parts:

- 3 metal Fixation Devices; each preloaded with a spider fastener composed of metal and includes the MRI Safety Information that is stated in the labeling.
- Plastic Handle; connects to the Fixation Device.
- Surgical mesh composed of monofilament polypropylene material; cut in a rectangular shape of 8x20cm.

The device is introduced through a 5mm trocar in a laparoscopic approach. The mesh is attached to the vaginal vault and the vagina is pulled towards the posterior pelvic bony part. The other end of the mesh is attached to the promontorium, using two fixation points, to restore the normal anatomical position of the uterus and cervix.

The EndoFast Reliant™ LAP (Laparoscopic) is a sterile, single use system which consists of the following parts:

- 3 metal Fixation Devices; each preloaded with a spider fastener composed of metal and include the MRI Safety Information that is stated in the labeling.
- Plastic Handle; connects to the Fixation Device.

The fasteners are introduced through a 5mm trocar in laparoscopic procedures.

Intended Use:
The EndoFast Reliant™ SCP is indicated for fixation of surgical mesh to tissue for tissue reinforcement during a laparoscopic Sacrocolpopexy approach.

The EndoFast Reliant™ LAP is indicated for fixation of surgical prosthetic material to tissues for tissue reinforcement during a laparoscopic Sacrocolpopexy approach.

Technological Characteristics:
The technological characteristics of the EndoFast Reliant™ SCP and EndoFast Reliant™ LAP are similar to those of the EndoFast Reliant™ System cleared under K080836. The dimensions of the spider fasteners and fixation device in the EndoFast

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Reliant™ SCP and EndoFast Reliant™ LAP have been decreased to accommodate a laparoscopic approach to be used in Sacrocolpopexy procedures. In addition, the shape of the fixation device in the EndoFast Reliant™ SCP and EndoFast Reliant™ LAP has been changed to accommodate a laparoscopic approach to be used in Sacrocolpopexy procedures.

Performance Testing:

The appropriate tests to determine substantial equivalence were completed. These include testing in accordance with Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh (March 22, 1999) and tests designed by the company to address substantial equivalence.

1. **The following non-clinical tests have been performed: Performance Tests:**
   a) Functional Characteristics Test to demonstrate appropriate functionality characteristics of EndoFast Reliant SCP after sterilization, Vibration and Drop test and a shelf life study.
   b) EndoFast Reliant SCP Fastener Support Endurance to Cyclic Loads to validate the endurance of the SCP Spider Fastener in supporting the cyclic load on the surgical mesh.
   c) SCP Fastener Deployment Reliability and Pull-Out Force Test to verify the deployment reliability and pullout force required for fastener failure, and to verify that the surgical mesh and the artificial tissue have no influence/ effect on the deployment of the Fastener of the SCP Fixation Device
   d) SCP Fixation Device and Handle Reliability and Force Test to verify the reliability of the SCP Fixation Device and the Handle that is attached to it in deploying the Fasteners without fault and to test the force applied during the deployment.
   e) Two cadaver studies were performed utilizing the EndoFast Reliant™ SCP.
   f) Comparative pull-out tests were conducted in order to assess the new products' equivalency with predicate devices.
2. **Gamma Sterilization Validation** for the Surgical Instruments - Using a Radiation dose of 25 kGy in order to assure products' SAL 10^{-6}.
3. **EtO Sterilization Validation** for the Sujrgical Mesh - Using Overkill Approach in order to assure products' SAL 10^{-6}.
4. **Shelf Life Tests** – Using accelerating aging in order to assure the products' adequate performances during their shelf life.
5. **Biocompatibility** – The products' were evaluated with accordance to ISO 10993-1 and FDA Blue Book Memorandum, G95-1.
6. **MR compatibility** – In order to assure the safe use of the device at MRI environment.

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Conclusion:

Israel Biomedical Innovations Ltd. believes that, based on the information provided in this submission, the EndoFast Reliant™ SCP and the EndoFast Reliant™ LAP are substantially equivalent to their predicate devices without raising any new safety and/or effectiveness issue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 29, 2013

IBI Israel Biomedical Innovations Ltd.
% Elissa Burg
VP Quality Assurance and Regulatory Affairs
2 Ha-Eshel Street, P.O. Box 3081
CAESAREA INDUSTRIAL PARK 38900
ISRAEL

Re: K130059
Trade/Device Name: EndoFast Reliant™ SCP, Endo Fast Reliant™ LAP
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: Class II
Product Code: PBQ, OTO
Dated: June 10, 2013
Received: June 17, 2013

Dear Elissa Burg,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130059

Device Name: EndoFast Reliant™ SCP
* **SCP** = Sacrocolpopexy

Indications for Use:

The EndoFast Reliant™ SCP is indicated for fixation of surgical mesh to tissue for tissue reinforcement during a laparoscopic Sacrocolpopexy approach.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130059

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130059

Device Name: EndoFast Reliant™ LAP
*** LAP** = Laparascopic

Indications for Use:

The EndoFast Reliant™ LAP is indicated for fixation of surgical prosthetic material to tissues for tissue reinforcement during a laparoscopic Sacrocolpopexy approach.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130059